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GENERAL REVIEW AND ENFORCEMENT POLICIES

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CENTER APPEALS PROCEDURE GUIDE

During review of an application, CVM personnel may communicate with the applicant concerning perceived deficiencies in the application. Occasionally applicants may question the need for additional information or disagree with the request. It is the Center's intention and policy that negotiations between the review group and the sponsor be the preferred method of resolution of differences regarding science or policy. These procedures represent CVM's interpretation of its responsibility to resolve disputes under 21 CFR 10.75 if the applicant is not satisfied with a Center decision.

1. Purpose:

The purpose of this guide is to provide for a review process for a drug applicant when the applicant disagrees with a decision regarding science or policy communicated in writing.

2. CVM Appeals Procedure:

When an applicant and reviewing branch/group conclude that an impasse exists, the applicant may submit a written appeal to the Division Director responsible for the Team/group that communicated the disputed decision to them. This initial appeal should include documentation of the applicant's viewpoint. If the documentation contains new information, however, the file will be remanded to the review group for evaluation.

- a. If the issue at disagreement involves animal safety or drug effectiveness, the Division Director will have the responsibility for preparing a written response to the applicant's appeal and for obtaining the concurrence of his or her Office Director with that response.
- b. If the issue involves one of the specialty Divisions, the Division Director will forward the appeal to the Director of the appropriate Division who will then be responsible for preparation of the response. This response will be transmitted back to the original Division for administrative handling as described below.
- c. A decision by the appropriate Office Director must be rendered within 40 calendar days of receipt of formal appeal.

- (1) If the Office Director concurs with the applicant's position on an issue, the Division Director in NADE or S&C will take appropriate action implementing the concurrence.
- (2) If the Office Director's response does not grant any relief to the applicant, the Division Director will notify the applicant by telephone and will forward the issue to HFV-2 for consideration by the CVM Appeals Committee.
- (3) If the Office Director's response grants the applicant partial relief, or offers a compromise solution to the issue, this will be communicated to the applicant by the Division Director. In these cases, it will be incumbent upon the applicant to continue the appeals process to the CVM Appeals Committee should he/she desire to do so.

3. CVM Appeals Committee Procedures:

- a. The CVM Appeals Committee will consist of the CVM Deputy Director, who will act as chairperson, and three additional Center management officials appointed by the Chair. Selection of these individuals will be on an ad hoc basis, subject to the issue involved. It is expected that the Committee will consult on an as needed basis with others, inside as well as outside of the Agency, who possess expertise in areas bearing on the matter under consideration.
- b. The applicant will be offered the opportunity to meet with the Appeals Committee and be accompanied by their own consultants. These meetings would provide an opportunity for a free exchange of information and views between the Agency and the sponsor. The meeting should be structured to allow for presentation by the applicant, input by appropriate Center personnel appropriate discussion, and finally a closed session for Committee deliberations. This format should be established and widely disseminated by the Committee to provide for consistent consideration of each issue presented to the Committee.
- c. Following the meeting, the CVM Deputy Director, with the advice of the Committee, will decide the issue and take whatever action is appropriate to implement the decision. A good faith effort to decide issues within 20 calendar days of their referral to the Committee will be made.

- d. The drug applicant has the option, at his/her discretion and initiative, to appeal the CVM Appeals Committee decision to the Center Director.